

University of Groningen

**Can diabetes management be safely transferred to practice nurses in a primary care setting?  
A randomised controlled trial**

Houweling, Sebastiaan T.; Kleefstra, Nanne; van Hateren, Kornelis J. J.; Groenier, Klaas H.;  
Meyboom-de Jong, Betty; Bilo, Henk J. G.

*Published in:*  
Journal of Clinical Nursing

*DOI:*  
[10.1111/j.1365-2702.2010.03562.x](https://doi.org/10.1111/j.1365-2702.2010.03562.x)

**IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.**

*Document Version*  
Publisher's PDF, also known as Version of record

*Publication date:*  
2011

[Link to publication in University of Groningen/UMCG research database](#)

*Citation for published version (APA):*

Houweling, S. T., Kleefstra, N., van Hateren, K. J. J., Groenier, K. H., Meyboom-de Jong, B., & Bilo, H. J. G. (2011). Can diabetes management be safely transferred to practice nurses in a primary care setting? A randomised controlled trial. *Journal of Clinical Nursing*, 20(9-10), 1264-1272. <https://doi.org/10.1111/j.1365-2702.2010.03562.x>

**Copyright**

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

**Take-down policy**

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

## DIABETES

**Can diabetes management be safely transferred to practice nurses in a primary care setting? A randomised controlled trial**

Sebastiaan T Houweling, Nanne Kleefstra, Kornelis JJ van Hateren, Klaas H Groenier, Betty Meyboom-de Jong and Henk JG Bilo

**Aims and objectives.** To determine whether the management of type 2 diabetes mellitus in a primary care setting can be safely transferred to practice nurses.

**Background.** Because of the increasing prevalence of type 2 diabetes mellitus and the burden of caring for individual patients, the demand type 2 diabetes mellitus patients place on primary health care resources has become overwhelming.

**Design.** Randomised controlled trial.

**Methods.** The patients in the intervention group were cared for by practice nurses who treated glucose levels, blood pressure and lipid profile according to a specified protocol. The control group received conventional care from a general practitioner. The primary outcome measure was the mean decrease seen in glycated haemoglobin (HbA1c) levels at the end of the follow-up period (14 months).

**Results.** A total of 230 patients was randomised with 206 completing the study. The between-group differences with respect to reduction in HbA1c, blood pressure and lipid profile were not significant. Blood pressure decreased significantly in both groups; 7.4/3.2 mm Hg in the intervention group and 5.6/1.0 mm Hg in the control group. In both groups, more patients met the target values goals for lipid profile compared to baseline. In the intervention group, there was some deterioration in the health-related quality of life and an increase in diabetes-related symptoms. Patients being treated by a practice nurse were more satisfied with their treatment than those being treated by a general practitioner.

**Conclusion.** Practice nurses achieved results, which were comparable to those achieved by a general practitioner with respect to clinical parameters with better patient satisfaction.

**Relevance to clinical practice.** This study shows that diabetes management in primary care can be safely transferred to practice nurses.

**Key words:** nurses, nursing, randomised controlled trial, type 2 diabetes mellitus

Accepted for publication: 19 August 2010

**Introduction**

Type 2 diabetes mellitus (T2DM) is a chronic, progressive disorder, which causes considerable morbidity and mortality

(Kannel & McGee 1979, Nathan *et al.* 1997). The world-wide prevalence of T2DM is high and is still increasing (Wild *et al.* 2004, Baan *et al.* 2009). In The Netherlands, more than 700,000 patients (~4% of the population) currently have

**Authors:** *Sebastiaan T Houweling*, MD, PhD, Assistant Professor and General Practitioner, Diabetes Centre, Isala Clinics; Langerhans Medical Research Foundation, Zwolle and General Practice Sleeuwijk, Sleeuwijk; *Nanne Kleefstra*, MD, PhD, Assistant Professor, Diabetes Centre, Isala Clinics, Zwolle and Langerhans Medical Research Foundation, Zwolle; *Kornelis JJ van Hateren*, MD, General Practitioner in Training, Diabetes Centre, Isala Clinics, Zwolle; *Klaas H Groenier*, MSc, PhD, Statistician, Department of General Practice, University Medical Center Groningen, Groningen; *Betty Meyboom-de Jong*, MD, PhD, Professor, Department of

General Practice, University Medical Center Groningen, Groningen; *Henk JG Bilo*, MD, PhD, FRCP, Professor and Internist, Diabetes Centre, Isala Clinics, Department of Internal Medicine, Isala Clinics, Zwolle and Department of Internal Medicine, University Medical Center Groningen, Groningen, The Netherlands

**Correspondence:** Kornelis JJ van Hateren, General Practitioner in Training, Diabetes Centre, Isala Clinics, PO Box 10400, 8000 GK Zwolle, The Netherlands. Telephone: +31 38 4242518.

**E-mail:** k.j.j.van.hateren@isala.nl

a diagnosis of diabetes, and this number will increase to 1.3 million patients by 2025 (Baan *et al.* 2009). With an estimated total population of 16.9 million people in 2025, almost 8% of the population will have diabetes. Worldwide, the total number of patients with diabetes is projected to rise from 171 million in 2000 (2.8%) to 366 million in 2030 (4.4%) (Wild *et al.* 2004). The development of new measures to lower the risk of cardiovascular disease has become increasingly important over the past decades. Accordingly, the current guidelines for the treatment of T2DM emphasise the aggressive treatment of important cardiovascular risk factors such as hypertension and dyslipidemia (Rutten *et al.* 2006). Because of the increasing prevalence and the burden of caring for individual patients, the demand T2DM patients place on primary health care resources has become overwhelming. This led to the consideration of transferring certain tasks, previously performed exclusively by physicians, to other medical professionals such as practice nurses (PNs). Approximately 62% of general practices in The Netherlands presently employ PNs (Hingstman & Kenens 2007). One of their main tasks is caring for patients with diabetes mellitus (Houweling *et al.* 2006, Meulepas *et al.* 2006, Van den Berg & Simkens 2006, Van Avendonk *et al.* 2007). The Netherlands has not expanded the scope of nurses as much as has been carried out in some countries such as the UK, the USA and Sweden, where nurses are permitted to prescribe medications (Kuebler 2003, Wilhelmsson & Foldevi 2003, Latter & Courtenay 2004). Dutch law does not allow nurses to write prescriptions. Although diabetes care has become highly dependant on PNs nowadays, only a few quality of care comparison studies have been conducted in The Netherlands. With this study, we wanted to test the hypothesis that the management of T2DM in a primary care setting can be safely transferred to PNs, without compromising the quality of clinical care, health-related quality of life (HRQOL) or patient satisfaction.

## Methods

### Study design

This study was a pragmatic randomised controlled trial to investigate the effects of transferring diabetes care to PNs in a primary care setting.

### Sampling

All participants in this study were patients with T2DM from a group practice with five general practitioners (GPs) in the north-east region of The Netherlands. Eligible patients were

selected using the GPs' patient information system and the local pharmacy. The initial selection included patients with a diagnosis of diabetes, patients who were on medication for diabetes and patients whose glycated haemoglobin (HbA1c) levels had been measured in the last three years. The exclusion criteria included (1) no diagnosis of diabetes, (2) type 1 diabetes, (3) diabetes not being treated in the primary health care setting, (4) the inability to participate in the study because of old age or comorbidity, in the opinion of the GP and (5) not being willing to return for follow-up.

### Intervention and control group

The patients in the intervention group were primarily treated by two PNs, who were both PNs without any special training in the treatment of diabetes prior to the start of this trial. At the beginning of the trial, the PNs received one week of training on a detailed treatment and management protocol aimed at optimising glucose, blood pressure and lipid profile regulation and eye and foot care in patients with diabetes (Houweling *et al.* 2004). The training aimed to educate the PNs to a level comparable to the level of a GP, so they would be able to provide diabetes care without supervision. The protocol was based on the guidelines published by the Dutch College of General Practitioners and on those from the Dutch Diabetes Federation (Rutten *et al.* 1999, Dutch Diabetes Federation 2000). For the purposes of this trial, the PNs were permitted to prescribe 14 different medications and to adjust dosages for a further 30. They were also allowed to order laboratory tests. The PNs were specifically not permitted to prescribe insulin, but were able to adjust the dosage. The control group received standard care from a GP. If the initiation of insulin therapy was indicated in any patient in either group, he or she was referred to an internist.

### Primary and secondary outcome measures

The primary endpoint was the mean decrease seen in HbA1c levels at follow-up compared with baseline. Secondary endpoints were blood pressure, cholesterol and cholesterol/high density lipoprotein (HDL)-ratio, proportion of patients achieving target ranges of glycaemic control (HbA1c below 7% and 8.5%, respectively), blood pressure (below 140/90 mmHg) and lipid profile (variable, depending on total cardiovascular risk and recommendations according to primary or secondary prevention). The following indicators were also looked at the proportion of patients: (1) referred to an ophthalmologist after not having visited one for the last two years, (2) in whom measures were taken for feet at-risk, (3) referred to an internist for starting insulin therapy,

(4) whose diabetic, antihypertensive and/or lipid lowering drugs had been intensified. Other secondary endpoints included measures of HRQOL, diabetes-related symptoms, patients' satisfaction and health care consumption (number of patient visits, number of contacts between PNs and GP).

### Measures

All subjects were seen prior to any intervention, before being randomly assigned to one of the two study groups and after 14 months (T2). The duration of T2DM, any diabetes medication(s), general medication(s) and the date of the last retina control were recorded at baseline. The patients were weighed clothed without shoes. Height was measured without shoes, and blood pressure was measured with the patient in a sitting position. Initially, blood pressure was measured twice in both arms, with an interval between measurements of at least 15 seconds. The mean of the two blood pressure readings was calculated for each arm. When there was a difference of more than 10 mmHg between the systolic and/or the diastolic blood pressures, the blood pressure during follow-up was measured in the arm with the highest blood pressure. When the difference was less than 10 mmHg, either arm could be used for the measurements at T2. A calibrated and validated Omron M5-I (HEM-757) automatic blood pressure device was used to measure blood pressure (El Assaad *et al.* 2003). To assess the risk of developing diabetic foot symptoms, both the dorsalis pedis artery and the posterior tibial artery were palpated and sensibility was tested using Semmes Weinstein monofilaments. HbA1c, serum total cholesterol, low-density lipoprotein, HDL, triglycerides, alanine aminotransferase and creatinine levels were measured according to standard hospital procedures. HRQOL was assessed with the Short Form 36 questionnaire (SF-36). The SF-36 is a validated generic HRQOL questionnaire that includes both mental and physical factors (Ware & Sherbourne 1992, Aaronson *et al.* 1998). To measure the presence and the perceived burden of diabetes-related symptoms, the revised version of the type 2 Diabetes Symptom Checklist (DSC-type 2) was used (Grootenhuis *et al.* 1994). Satisfaction with diabetes care was assessed using the Patients' Evaluation of the Quality of Diabetes Care (PEQD) (Pouwer & Snoek 2002). Patients in the GP group were asked about the number of visits. This number was multiplied by 10 minutes, which is the standard average time the five GPs scheduled for each of their patients, to estimate the total duration of the visits. In the intervention group, similar information was recorded by the involved PN. The PNs also kept records of the number and duration of consultations with the GP.

### Randomisation and sample size power

Eligible patients were informed by their GP or PN about the study. Patients willing to participate were then randomised by two independent medical investigators (STH and NK). The patient population was randomised using non-transparent, closed envelopes containing sequential numbers. Subjects with even numbers were assigned to the intervention group, and those with odd numbers were assigned to the control group. Two hundred and sixteen patients were required for the detection of a 0.5%-point difference in mean HbA1c between groups at T2 with a power of 80%, alpha 5% (two-sided) and an assumed standard deviation of 1.3. This calculation was based on the mean HbA1c of patients in the primary care health system in the Zwolle region (7.5%, SD 1.3) (Ubink-Veltmaat *et al.* 1995).

### Statistical analyses

Statistical analyses were performed using spss 15.0 (SPSS Inc., Chicago, IL, USA) for Windows. For longitudinal analyses, the general linear model (GLM repeated measures) for continuous variables and the McNemar test for changes in dichotomous variables were used. To study changes in HRQOL, diabetes-related symptoms and quality of diabetes care, we used the Mann-Whitney *U* tests for analyses between groups and the Wilcoxon signed rank tests for changes from baseline within groups because of some skewed outcomes. The internal consistency of the item scores was assessed using Cronbach's alpha (Cronbach 1951); reported *p*-values are two tailed.

### Ethical considerations

The Medical Ethics Committee of the Isala Clinics, Zwolle, The Netherlands concluded that this study did not need formal approval, because they had previously approved a study with a similar design performed in the secondary health care setting (Houweling *et al.* 2009). All patients gave written informed consent, and all data were analysed anonymously.

### Results

Figure 1 shows the number of participants involved throughout the study. After the assessment of eligibility, 133 patients were excluded because of treatment by an internist ( $n = 76$ ), no diagnosis of diabetes ( $n = 26$ ), old age or comorbidity ( $n = 21$ ) and unwillingness to participate ( $n = 10$ ). Of the 230 randomised patients, 24 patients were lost to follow-up (14 in the intervention group and 10 in the control group). A total of 206 patients, 102 in the intervention group and

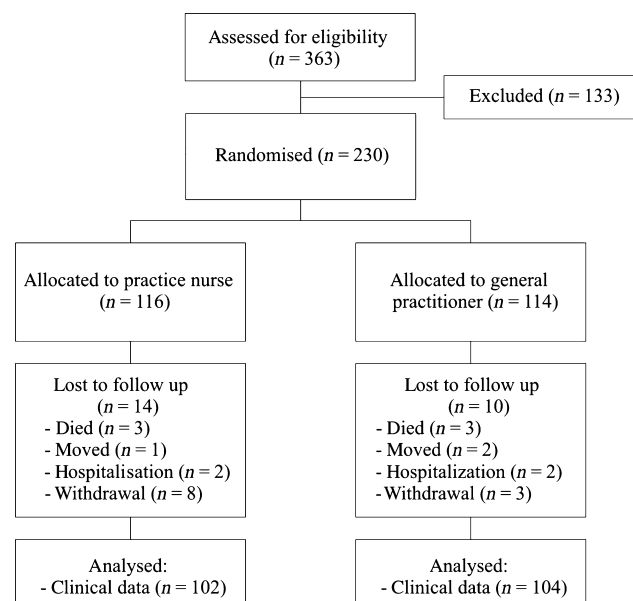


Figure 1 Flow diagram. Number of participants in stages of the trial.

104 in the control group were used for analysis. The groups were comparable with respect to age, gender, T2DM duration, body mass index (BMI), blood pressure, HbA1c and lipid profile (Table 1). However, more patients in the PN group had feet at-risk compared to the GP group.

After a follow-up of 14 months, the mean systolic and diastolic blood pressures were significantly lower in both groups (Table 2). The mean BMI (95% confidence interval) significantly declined in the control group with 0.3 kg/m<sup>2</sup> (0.1–0.6). The other outcome indicators did not change, and any differences between the groups were not significant. In addition, the proportion of patients meeting the predefined blood pressure goal of <140 mmHg systolic significantly

increased in the PN group (Table 3). In both groups, more patients met the target values goals for lipid profile when compared to the data obtained at baseline. The differences between the groups were not significant.

Table 4 presents the process indicators in both treatment groups. Patients who had their last retina control more than two years ago were referred to the ophthalmologist in 70.6% of all cases by the PNs, compared to 36.7% by the GPs ( $p = 0.007$ ). Measures to prevent the development of diabetic foot symptoms were taken in 56.7% of the feet at-risk cases in the PN group and in 26.5% in the GP group ( $p = 0.001$ ). The PNs referred more patients to the internist for the initiation of insulin therapy than the GPs ( $p = 0.015$ ). The PNs generally stepped up the treatment for hypertension and diabetes, whereas the GPs more often targeted the lipid profile. However, the difference in lipid treatment between the groups was not significant.

At both baseline and follow-up, 178 patients (86%) completed the SF-36, 168 patients (82%) completed the Diabetes Symptom Checklist and 179 patients (87%) completed the satisfaction survey. There were no significant differences between the baseline and follow-up results for all of the HRQOL items (SF-36) reported by the subjects in the control group (Table 5). In the PN group, four areas were adversely affected: physical functioning, role physical, vitality and the physical component score. No differences were seen in the HRQOL results over time between the two groups, except for the Physical Component Score which was lower in the intervention group. In both groups, significant differences were found at follow-up for some of the Diabetes Symptom Score dimensions (data not shown). After 14 months, the mean 'fatigue' and 'cognitive distress' sub-dimension scores and the total score were lower in each group, although no difference was seen between the groups. The internal

Table 1 Baseline characteristics

	PN	GP
Gender (male)	54/102 (52.9)	44/104 (42.3)
Age (year)	67.1 ± 11.0	69.5 ± 10.6
Diabetes duration (year) (mean ± SD, median (25%–75%))	7.2 ± 6.6 6.0 (2.0–10.0)	7.8 ± 7.3 5.0 (3.0–13.0)
Percentage patients with last retina control > 24 months ago	36/102 (35.3)	30/102 (29.4)
Percentage patients with feet at-risk	64/101 (63.4)	50/102 (49.0)
Body mass index (kg/m <sup>2</sup> )	30.6 ± 5.3	30.3 ± 4.5
Systolic blood pressure (mmHg)	157.5 ± 20.4	161.3 ± 24.8
Diastolic blood pressure (mmHg)	87.2 ± 10.7	87.0 ± 11.2
HbA1c (%)	7.6 ± 1.3	7.4 ± 1.3
Total cholesterol (mmol/l)	5.4 ± 1.1	5.4 ± 1.0
Cholesterol/HDL ratio	4.4 ± 1.1	4.1 ± 1.2

Data are absolute numbers (%) or mean ± SD unless stated otherwise.

GP, general practitioner; HDL, high density lipoprotein; PN, practice nurse.

**Table 2** Mean change scores of outcome indicators by treatment group

	PN		GP		<i>p</i> -value difference between groups
	Baseline	Mean paired difference T2 (95% CI)	Baseline	Mean paired difference T2 (95% CI)	
Systolic BP (mmHg)	157.5 ± 20.4	-7.4 (-3.8, -10.9)	161.3 ± 24.8	-5.6 (-2.3, -8.8)	0.122
Diastolic BP (mmHg)	87.2 ± 10.7	-3.2 (-1.3, -5.2)	87.0 ± 11.2	-1.0 (-0.8, -2.8)	0.391
BMI (kg/m <sup>2</sup> )	30.6 ± 5.3	-0.2 (-0.5, 0.1)	30.3 ± 4.5	-0.3 (-0.6, -0.1)	0.377
HbA1c (%)	7.6 ± 1.3	-0.09 (-0.3, 0.1)	7.4 ± 1.3	0.03 (-0.2, 0.3)	0.423
Total cholesterol (mmol/l)	5.4 ± 1.1	-0.1 (-0.3, 0.1)	5.4 ± 1.0	-0.05 (-0.2, 0.1)	0.321
Cholesterol/HDL	4.4 ± 1.1	0.03 (-0.1, 0.2)	4.1 ± 1.2	0.07 (-0.1, 0.2)	0.385

BMI, body mass index; GP, general practitioner; HDL, high density lipoprotein; PN, practice nurse.

**Table 3** Per cent of patients meeting target values

Goal	PN			GP		
	T0	T2	<i>p</i> -value	T0	T2	<i>p</i> -value
HbA1c						
<7.0	38/102 (37.3)	35/102 (34.3)	0.678	48/104 (46.2)	45/104 (43.3)	0.629
≤8.5	79/102 (77.5)	88/102 (86.3)	0.078	84/104 (80.8)	91/104 (87.5)	0.143
Blood pressure						
<140/90	17/102 (16.7)	26/102 (25.5)	0.049	19/104 (18.3)	22/104 (21.2)	0.629
Lipid profile						
*	73/102 (71.6)	81/102 (79.4)	0.008	78/104 (75.0)	88/104 (84.6)	0.002

Data are absolute numbers (%).

GP, general practitioner; PN, practice nurse.

\*Individual target values according to Dutch guidelines in which an indication for treatment in men between 50–70 years of age and women between 50–75 years of age with a 25% chance of developing cardiovascular disease in 10 years. During treatment, the target value for the cholesterol level is <5 mmol/l.

consistency of the 14 PEQD items was high with a Cronbach's alpha of 0.97. The total satisfaction sum score for the PNs was 66.4% and for the GPs 51.7%.

The mean number of visits was 6.1 in the PN group and 2.8 in the GP group ( $p < 0.001$ ). As a consequence, the total duration of the visits was also significantly higher in the PN group. In some cases, the protocol being followed by the PN indicated that consultation with a GP was necessary. The median number of these consultations per patient was 1.4 (25–75 quartiles: 0.0–2.0) with a median time of 1.0 (25–75 quartiles: 0.0–3.3) minute.

## Discussion

This is the first randomised controlled study where the care provided by a PN, with an almost complete shift of diabetes

care, is compared with care provided by a GP in a population of patients with T2DM in the primary health care setting in The Netherlands. The results show that a nurse, when following specific guideline protocols, achieves results which are comparable to those achieved by a GP with respect to blood pressure, glucose and lipid profile regulation. Furthermore, most of the results regarding the process indicators were remarkably better in the group cared for by a nurse. Although patients in the PN group were more satisfied with the care they received than the patients in the control group, the physical component summary of the SF-36 was better in the GP group.

The deterioration of the SF-36 physical component scores seen in the PN group, compared with the GP group, was unexpected and has not previously been described in the literature. Although it was not a separate health dimension that got worse in the PN group compared to the GP group, but only a component summary suggesting an overall direction of the 'physical' quality of life, it is interesting to speculate about the underlying cause. It is possible that participating in this study forced the patients to focus more on their diabetes. Perhaps, they became more aware of the complications of diabetes in the long term with its physical consequences. Because patients in the intervention group visited their care provider (the PNs) more often and for longer periods of time, the effects are probably more pronounced in this group. Further investigation is necessary to answer the question of whether the potential negative effects on HRQOL are caused by the PNs providing the treatment or whether it is a temporary phenomenon.

Confounding factors may contribute to the explanation for the differences seen between the groups with respect to treatment satisfaction and the process indicators. An important confounder is probably the amount of time given to each patient. The mean number of patient visits was 6.1 in the PN group vs. 2.8 in the GP group ( $p < 0.001$ ), and a PN visit lasted an average of 21 minutes compared with 10 minutes



Table 4 Process indicators by treatment group

	PN	GP	<i>p</i> -value difference between groups
Patients with last retina control >24 months ago ( <i>n</i> = 64) referred to an ophthalmologist	24/34 (70.6)	11/30 (36.7)	0.007
Patients with feet at-risk ( <i>n</i> = 109) in whom measures were taken	34/60 (56.7)	13/49 (26.5)	0.001
Patients referred to an internist for starting insulin therapy	10/102 (9.8)	2/104 (1.9)	0.015
Patients with a HbA1c $\geq 7$ at baseline ( <i>n</i> = 120), in whom glucose lowering therapy was intensified	53/64 (82.8)	28/56 (50.0)	<0.001
Patients with a BP > 140/90 at baseline ( <i>n</i> = 170) in whom blood pressure lowering therapy was intensified	42/85 (49.4)	24/85 (28.2)	0.005
Patients not meeting the target values for lipid profile at baseline ( <i>n</i> = 55), in whom lipid lowering therapy was intensified	13/29 (44.8)	13/26 (50.0)	0.147

Data are absolute numbers (%).

GP, general practitioner; PN, practice nurse.

Table 5 Quality of life scores (SF-36) by treatment group

SF-36 scale score	PN <i>n</i> = 85			GP <i>n</i> = 93		
	T0	T2	<i>p</i> -value	T0	T2	<i>p</i> -value
	Mean $\pm$ SD Median (25–75%)	Mean $\pm$ SD Median (25–75%)		Mean $\pm$ SD Median (25–75%)	Mean $\pm$ SD Median (25–75%)	
Physical functioning	71.8 $\pm$ 25.8 83.3 (52.5–90.0)	64.9 $\pm$ 28.9 75.0 (40.0–90.0)	0.001	69.0 $\pm$ 23.5 75.0 (53.8–90.0)	65.2 $\pm$ 27.9 70.0 (45.0–90.0)	0.078
Social functioning	81.6 $\pm$ 24.0 87.5 (68.8–100)	81.8 $\pm$ 20.5 87.5 (62.5–100)	0.761	80.1 $\pm$ 22.6 87.5 (62.5–100)	77.6 $\pm$ 21.2 81.3 (62.5–100)	0.305
Role physical	69.3 $\pm$ 40.0 100 (25.0–100)	56.8 $\pm$ 43.3 75.0 (0.0–100)	0.008	64.0 $\pm$ 43.8 100 (25.0–100)	64.7 $\pm$ 42.0 100 (25.0–100)	0.865
Role emotional	78.9 $\pm$ 35.9 100 (66.7–100)	72.1 $\pm$ 41.6 100 (33.3–100)	0.119	77.7 $\pm$ 37.4 100 (66.7–100)	73.3 $\pm$ 39.9 100 (33.3–100)	0.311
Mental health	79.3 $\pm$ 16.6 80.0 (72.0–92.0)	77.7 $\pm$ 17.6 80.0 (64.0–92.0)	0.142	77.6 $\pm$ 16.9 84.0 (64.0–92.0)	75.6 $\pm$ 18.7 80.0 (60.0–92.0)	0.283
Vitality	67.6 $\pm$ 19.9 70.0 (50.0–80.0)	62.8 $\pm$ 21.8 65.0 (45.0–80.0)	0.012	67.9 $\pm$ 18.8 70.0 (55.0–80.0)	64.8 $\pm$ 20.9 70.0 (50.0–80.0)	0.067
Bodily pain	72.9 $\pm$ 26.4 80.0 (52.0–100)	71.6 $\pm$ 25.3 74.0 (52.0–100)	0.388	74.5 $\pm$ 24.2 74.0 (51.0–100)	72.1 $\pm$ 22.9 74.0 (52.0–100)	0.687
General health	61.7 $\pm$ 19.7 66.0 (45.0–77.0)	60.2 $\pm$ 18.5 62.0 (48.5–72.0)	0.400	62.7 $\pm$ 16.4 62.0 (52.0–77.0)	63.5 $\pm$ 16.6 67.0 (52.0–77.0)	0.852
Physical component score	45.3 $\pm$ 9.9 48.1 (38.9–54.5)	43.0 $\pm$ 10.9 44.8 (34.9–52.1)	0.008	43.9 $\pm$ 9.4 45.2 (36.2–52.7)	44.7 $\pm$ 9.1 46.8 (37.5–52.1)	0.652
Mental component score	53.3 $\pm$ 8.9 55.9 (49.9–60.0)	52.0 $\pm$ 10.8 55.2 (46.8–60.5)	0.080	53.2 $\pm$ 9.5 56.3 (48.8–60.5)	52.2 $\pm$ 10.4 55.1 (46.8–59.5)	0.217

0 (worst health) to 100 (best health).

General linear model between groups NS for all variables, except for physical component score: *p* = 0.040.

GP, general practitioner; PN, practice nurse.

for a GP visit. On average, GPs spent a total of 28 minutes per patient during the study period of 14 months, whereas the PNs spent a total of 128 minutes. Treatment satisfaction is surely to be influenced by the amount of time spent by the health care provider. Furthermore, PNs had more time with their patients to achieve the treatment goals, and patients

probably had more time to ask questions and discuss any difficulties they encountered in their diabetes treatment. Another explanation may be that PNs tended to follow the protocol more strictly than the GPs. Take for example blood pressure management. In patients with a blood pressure > 140/90 at baseline, blood pressure lowering treatment was

intensified in 49.4% in the PN group compared to 28.2% in the GP group ( $p = 0.005$ ). Perhaps, PNs aggressively intensified blood pressure lowering therapy even in patients with only mildly elevated blood pressure levels, where GPs in the same situation may initially have opted for a wait-and-see policy.

Except for the possibility of confounding, our study has some other limitations. First of all, the required sample size to detect a 0.5%-point difference in HbA1c was a total of 216 patients. Unfortunately, we only have a complete follow-up of 206 patients. However, the difference in HbA1c (95% confidence interval) between groups after 14 months was 0.042% ( $-0.207; 0.265$ ). As the confidence interval does not include the possibility of a 0.5%-point difference in HbA1c between groups, we are able to make the conclusions as hypothesised. Second, the outcome assessors of the clinical variables (such as blood pressure) were not blinded to the intervention. For obvious reasons, blinding of the patients and care providers was not possible in our study.

Task delegation of diabetes management in primary health care has been investigated by Vrijhoef and van Son in The Netherlands (Vrijhoef *et al.* 2001, Van Son *et al.* 2004). However, nurses were not allowed to start or adjust medication in these studies. A Cochrane review from 2003 investigated the effect on the metabolic regulation of patients with diabetes when treatment was carried out by a nurse (Loveman *et al.* 2003). Only six studies were included in this review. Three of the studies in the review included patients with type 1 diabetes in a hospital setting. In the other three studies, the nurse was responsible only for delivering treatment recommendations to the primary physician, without being responsible for treating the patient. All the studies performed prior to 2002 were included in the Cochrane review.

In addition to this review, we discovered seven randomised studies in Medline, which were published between 2002–2009 (Davies *et al.* 2001, Davidson 2003, Gary *et al.* 2003, New *et al.* 2003, Taylor *et al.* 2003, Tobe *et al.* 2006, Cleveringa *et al.* 2008). Nurses were allowed to titrate medications according to an algorithm in three of the studies (Davidson 2003, Taylor *et al.* 2003, Tobe *et al.* 2006). The results when the treatment was administered by a nurse were comparable or superior to the results for patients receiving standard care from the GP. Although Tobe *et al.* selected primary care patients, the home care nurses involved were indirectly supervised by a specialist in hypertension (Tobe *et al.* 2006). Patients in the study by New *et al.* all received shared care at baseline and are therefore not representative of

typical type 2 diabetic populations in the primary health care setting (New *et al.* 2003). The study by Taylor *et al.* is therefore the only one which involved patients in the primary health care setting (Taylor *et al.* 2003). The nurses in Taylor *et al.*'s study were not permitted to prescribe new medication. More recently, another study was performed in The Netherlands (Cleveringa *et al.* 2008). This study investigated the effect of the Diabetes Care Protocol on HbA1c and cardiovascular risk factors. The Diabetes Care Protocol combines task delegation (PN), computerised decision support and feedback every 3 months. Changes in treatment were only performed by the PNs after they were approved by the GP.

## Relevance to clinical practice

In most published studies about nurse care management, the objective is to determine whether care provided by a nurse would lead to improved care for patients with diabetes. The question being considered in this study was not whether or not care delivered by a nurse would be better than care delivered by a GP, but whether such care would at least be comparable to the care provided by a GP. Furthermore, nurses were allowed to prescribe medication for the purposes of our study. Our results show that standardised care delivered by a specially trained nurse is a good alternative to standard care by a GP, as the short-term results with respect to the standard medical parameters were comparable and patient satisfaction was actually better when patients were treated by a nurse. We would like to recommend that PNs should be allowed to prescribe medications in The Netherlands, as is common practice in some other countries.

## Acknowledgements

This study was sponsored by the Medical Research Fund Zwolle, the Steering Committee Care Renewal from the Isala Clinics, and the Dutch Ministry of Health, Welfare and Sport.

## Contributions

Study design: STH, NK, BMJ, HJGB; data collection and analysis: STH, NK, KJJH, KHG and manuscript preparation: STH, NK, KJJH, KHG, BMJ, HJGB.

## Conflict of interest

We declare that we have no (financial) conflicts of interest.



## References

- Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, Sprangers MA, te Velde A & Verrips E (1998) Translation, validation and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. *Journal of Clinical Epidemiology* **51**, 1055–1068.
- Baan CA, van Baal PHM, Jacobs-van der Bruggen MAM, Verkleij H, Poos MJJc, Hoogveen RT & Schoemaker CG (2009) Diabetes mellitus in The Netherlands: an estimate of the present burden on health care and a prognosis for 2025. *Nederlands Tijdschrift voor Geneeskunde* **153**, A580.
- Cleveringa FGW, Gorter KJ, van den Donk M & Rutten GEHM (2008) Combined task delegation, computerized decision support and feedback improve cardiovascular risk for type 2 diabetic patients. *Diabetes Care* **31**, 2273–2275.
- Cronbach LJ (1951) Coefficient alpha and the internal structure of tests. *Psychometrika* **16**, 297–334.
- Davidson MB (2003) Effect of nurse-directed diabetes care in a minority population. *Diabetes Care* **26**, 2281–2287.
- Davies M, Dixon S, Currie CJ, Davis RE & Peters JR (2001) Evaluation of a hospital diabetes specialist nursing service: a randomized controlled trial. *Diabetic Medicine* **18**, 301–307.
- Dutch Diabetes Federation (2000) *Guidelines and Recommendations for Good Diabetes Care*, edition 2000: Dutch Diabetes Federation, Leusden.
- El Assaad M, Topouchian J, Le Dudal K, Labaki G & Asmar R (2003) Validation of the Omron © M5-I blood pressure device according to the international validation protocol. *Journal of Hypertension* **21**(Suppl. 4), S23.
- Gary TL, Bone LR, Hill MN, Levine DM, McGuire M, Saudek C & Brancati FL (2003) Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans. *Preventive Medicine* **37**, 23–32.
- Grootenhuis PA, Snoek FJ, Heine RJ & Bouter LM (1994) Development of a type 2 diabetes symptom checklist: a measure of symptom severity. *Diabetic Medicine* **11**, 253–261.
- Hingstman L & Kenens RJ (2007) Figures from the registration of general practitioners - survey 2007. NIVEL.
- Houweling ST, Kleefstra N, Verhoeven S, van Ballegooie E & Bilo HJG (2004) *Diabetes Care According to Protocol. Possibilities for Task Delegation*. Langerhans foundation, Zwolle.
- Houweling ST, Kleefstra N, van Ballegooie E, Verhoeven S, Bilo HJG & Meyboom-de Jong B (2006) Task reassignment in primary health care. Questionnaire administered to more than 400 medical support staff. *Huisarts en wetenschap* **49**, 118–122.
- Houweling ST, Kleefstra N, van Hateren KJ, Kooy A, Groenier KH, Ten Vergert E, Meyboom-de Jong B & Bilo HJ; Langerhans Medical Research Group (2009) Diabetes specialist nurse as main care provider for patients with type 2 diabetes. *Netherlands Journal of Medicine* **67**, 279–284.
- Kannel WB & McGee DL (1979) Diabetes and cardiovascular disease. The Framingham study. *Journal of the American Medical Association* **241**, 2035–2038.
- Kuebler KK (2003) The palliative care advanced practice nurse. *Journal of Palliative Medicine* **6**, 707–714.
- Latter S & Courtenay M (2004) Effectiveness of nurse prescribing: a review of the literature. *Journal of Clinical Nursing* **13**, 26–32.
- Loveman E, Royle P & Waugh N (2003) Specialist nurses in diabetes mellitus. *Cochrane Database of Systematic Reviews* **2**, CD003286.
- Meulepas M, Braspenning J, Vlek H, Lucas A, de Grauw W & Grol R (2006) A model for the care of patients with diabetes mellitus type 2 in the primary health care setting: adaptable and achievable. *Huisarts en wetenschap* **49**, 356–360.
- Nathan DM, Meigs J & Singer DE (1997) The epidemiology of cardiovascular disease in type 2 diabetes mellitus: how sweet it is ... or is it? *Lancet* **350**(Suppl. 1), 4–9.
- New JP, Mason JM, Freemantle N, Teasdale S, Wong LM, Bruce NJ, Burns JA & Gibson JM (2003) Specialist nurse-led intervention to treat and control hypertension and hyperlipidemia in diabetes (SPLINT): a randomized controlled trial. *Diabetes Care* **26**, 2250–2255.
- Pouwer F & Snoek FJ (2002) Patients' Evaluation of the Quality of Diabetes Care (PEQD): development and validation of a new instrument. *Quality and Safety in Health Care* **11**, 131–136.
- Rutten GEHM, Verhoeven S, Heine RJ, DeGrauw WJC, Cromme PVM, Renders K, Van Ballegooie E & Wiersma TJ (1999) NHG practice guideline diabetes mellitus type 2 (first revision). *Huisarts en wetenschap* **42**, 67–84.
- Rutten GEHM, de Grauw WJC, Nijpels G, Goudswaard AN, Uitewaal PJM, van der Does FEE, Heine RJ, Van Ballegooie E, Verduijn MM & Bouma M (2006) NHG practice guideline diabetes mellitus type 2 (second revision). *Huisarts en wetenschap* **49**, 137–152.
- Taylor CB, Miller NH, Reilly KR, Greenwald G, Cuning D, Deeter A & Abascal L (2003) Evaluation of a nurse-care management system to improve outcomes in patients with complicated diabetes. *Diabetes Care* **26**, 1058–1063.
- Tobe SW, Pylypchuk G, Wentworth J, Kiss A, Szalai JP, Perkins N, Hartman S, Ironstand L & Hoppe J (2006) Effect of nurse-directed hypertension treatment among First Nations people with existing hypertension and diabetes mellitus: the Diabetes Risk Evaluation and Microalbuminuria (DREAM 3) randomized controlled trial. *Canadian Medical Association Journal* **174**, 1267–1271.
- Ubink-Veltmaat LJ, Bilo HJ, Groenier KH, Rischen RO & Meyboom-de Jong B (1995) Challenges in preventing cardiovascular complications in type 2 diabetes in primary care. *The European Journal of General Practice* **11**, 11–16.
- Van Avendonk MJP, Gorter KJ, van den Donk M & Rutten GEHM (2007) Not all general practices are organized to deliver optimal care for diabetes. Questionnaire. *Huisarts en wetenschap* **50**, 529–534.
- Van den Berg M & Simkens A (2006) Practice assistant and medical resident: who does what? *Huisarts en wetenschap* **49**, 397.
- Van Son L, Vrijhoef H, Crebolder H, van Hoef I & Beusmans G (2004)

- Supporting the general practitioner. A randomized controlled trial investigating the effects of a practice nurse on asthma, COPD and diabetes. *Huisarts en wetenschap* 47, 15–21.
- Vrijhoef HJ, Diederiks JP, Spreeuwenberg C & Wolffenbuttel BH (2001) Substitution model with central role for nurse specialist is justified in the care for stable type 2 diabetic outpatients. *Journal of Advanced Nursing* 36, 546–555.
- Ware JE Jr & Sherbourne CD (1992) The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care* 30, 473–483.
- Wild S, Roglic G, Green A, Sicree R & King H (2004) Global prevalence of diabetes: estimates for the year 2000 and projection for 2030. *Diabetes Care* 27, 2568–2569.
- Wilhelmsson S & Foldevi M (2003) Exploring views on Swedish district nurses' prescribing – a focus group study in primary health care. *Journal of Clinical Nursing* 12, 643–650.

*The Journal of Clinical Nursing* (JCN) is an international, peer reviewed journal that aims to promote a high standard of clinically related scholarship which supports the practice and discipline of nursing.

For further information and full author guidelines, please visit JCN on the Wiley Online Library website: <http://wileyonlinelibrary.com/journal/jocn>

### Reasons to submit your paper to JCN:

**High-impact forum:** one of the world's most cited nursing journals and with an impact factor of 1.194 – ranked 16 of 70 within Thomson Reuters Journal Citation Report (Social Science – Nursing) in 2009.

**One of the most read nursing journals in the world:** over 1 million articles downloaded online per year and accessible in over 7000 libraries worldwide (including over 4000 in developing countries with free or low cost access).

**Fast and easy online submission:** online submission at <http://mc.manuscriptcentral.com/jcnur>.

**Early View:** rapid online publication (with doi for referencing) for accepted articles in final form, and fully citable.

**Positive publishing experience:** rapid double-blind peer review with constructive feedback.

**Online Open:** the option to make your article freely and openly accessible to non-subscribers upon publication in Wiley Online Library, as well as the option to deposit the article in your preferred archive.